JUN 23 2000

Fresenius Combilines™ Low Volume Blood Tubing Set
510(k) Premarket Notification

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	95 Hayden Ave Two Ledgemont Center Lexington, MA 02420
Phone:	1-781-402-9068
Fax:	(781) 402-9082
Contact Person:	Arthur Eilinsfeld, Regulatory Affairs Manager
Date of Preparation:	September 21, 1999

B. Device Name:

Trade Name:	Fresenius Combilines Low Volume Blood Tubing Set
Common/Usual Name:	Low Volume Blood Tubing Set
Classification Name:	Blood Tubing Set, with and without Anti-regurgitation Valve

C. Predicate Device Name:

The predicate devices for the Fresenius Combilines Low Volume Blood Tubing Sets are:

- Medisystems Low Volume Arterial Blood Tubing Set (#K811839 and #K953823);
- Medisystems Low Volume Venous Blood Tubing Set (#K811839 and #K953823);
- Fresenius Combilines Hemodialysis Blood Tubing Sets (#K962081).

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D. Indications for Use:

The Fresenius Combilines Low Volume Blood Tubing Sets are intended for use as the extracorporeal blood circuit during hemodialysis. They are intended for single use only. The Low Volume Blood Tubing Sets are indicated for use with conventional and high flux negative pressure hemodialyzer equipment.

E. Substantial Equivalence:

1. Is the product a device?

YES - The Fresenius Combilines Low Volume Blood Tubing Sets are devices pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the Fresenius Combilines Low Volume Blood Tubing Sets is equivalent to the intended uses for the Medisystems Low Volume Blood Tubing Sets and for the Fresenius Combilines Hemodialysis Blood Tubing Sets.

Fresenius Combilines Low Volume Blood Tubing Set

Intended Use

The Fresenius Combilines Low Volume Blood Tubing Sets are intended for use as the extracorporeal blood circuit during hemodialysis. They are intended for single use only. The Low Volume Blood Tubing Sets are indicated for use with conventional and high-flux negative pressure hemodialyzer equipment.

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Medisystems Low Volume Blood Tubing Set (#K811839B and #K953823)

Intended Use

The blood tubing sets are intended for use with a blood access device and a medically approved flow-through treatment device (e.g. a hemodialyzer).

Fresenius Combilines Hemodialysis Blood Tubing Sets (#K962081)

Intended Use

The Combilines Hemodialysis Blood Tubing Set is intended for use as the extracorporeal blood circuit during hemodialysis. It is intended for single use only. The Combilines Hemodialysis Blood Tubing Set is indicated for use with conventional and high flux negative pressure hemodialyzer equipment.

3. **Does the device have technological characteristics that raise new types of safety or effectiveness questions?**

NO – The technological characteristics of the Fresenius Combilines Low Volume Blood Tubing Sets are equivalent to those of the Medisystems Low Volume Blood Tubing Sets. The components and features of the Fresenius Combilines Low Volume Blood Tubing Sets are equivalent to the Medisystems Low Volume Blood Tubing Sets. Furthermore, the materials, packaging and sterilization cycle of the Fresenius Combilines Low Volume Blood Tubing Sets are identical to those used in other commercially available Fresenius Combilines blood tubing sets.

4. **Does descriptive or performance information demonstrate equivalence?**

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the Fresenius Combilines Low Volume Blood Tubing Sets and demonstrates that they are substantially equivalent to the Medisystems Low Volume Blood Tubing Sets.

Art Eilinsfeld
Regulatory Affairs Manager

4/3/00
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2000

Mr. Arthur Eilinsfeld
Regulatory Affairs Manager
Fresenius Medical Care North America
Two Ledgemont Center
95 Hayden Avenue
Lexington, MA 02173

Re: K001107
Fresenius Combilines™ Low Volume
Blood Tubing Sets
Dated: April 3, 2000
Received: April 5, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJK

Dear Mr. Eilinsfeld:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius Combilines Low Volume Blood Tubing Sets

Indications for Use:

The Fresenius Combilines Low Volume Blood Tubing Sets are intended for use as the extracorporeal blood circuit during hemodialysis. They are intended for single use only. The Low Volume Blood Tubing Sets are indicated for use with conventional and high-flux negative pressure hemodialyzer equipment.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

Corporate Headquarters: Fresenius Medical Care, 95 Hayden Avenue, Lexington, MA 02420 Tel: 781 402 9000

Kapil Kammula for Dan Schultz
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001107